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United States  
Department of  
Agriculture

Animal and Plant  
Health Inspection  
Service

Veterinary Services

Center for Veterinary  
Biologics

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## CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 04-13

Subject: The Use of Minimum Age Animals in Licensure Studies

To: Biologics Licensees, Permittees, and Applicants  
Directors, Center for Veterinary Biologics

### I. PURPOSE

This notice informs licensees, permittees, and applicants of current Center for Veterinary Biologics (CVB) policy concerning the use of minimum age animals in the various studies conducted to support licensure of a product.

### II. BACKGROUND

Title 9 Code of Federal Regulations (9CFR) Part 112.2(a)(5) indicates that product labeling should provide full instructions for the proper use of the product, including vaccination schedules, warnings, and cautions. This notice clarifies the connection between vaccination schedules recommended on the labeling, and the use of minimum age animals in licensure studies. The issue of use of minimum age animals is discussed in Veterinary Services Memorandums 800.50, 800.202, and 800.204.

### III. POLICY

A minimum age for vaccination with the product should be established and indicated on the labeling to represent the proper use of the product. The minimum age for vaccination should be supported by data indicating the product is both safe and effective when given as indicated. The age of animals used in the safety and efficacy studies should be consistent. If the age is not consistent, the older age will be utilized for labeling purposes. In some cases, the younger age study may be referred to in the labeling.

For poultry, production animal products, and aquaculture products, minimum age animals should be used in the safety and efficacy studies.

For companion animal and equine products, minimum age animals should be used in the efficacy studies and should represent one-third of the animals used for the field safety study.

For production animal products for breeding animals, minimum age animals should be used in the efficacy studies, and should represent one-third of the animals used for the field safety study.



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For studies to support onset of immunity and duration of immunity label claims, minimum age animals should be used.

#### **IV. ACTION**

All outlines should indicate minimum ages in Section VI.D. Firms should bring their Outlines of Production into compliance with this notice before or at the next annual review of the Outline of Production. All outlines should specify this information by one year from the date of this notice.

Information in the Outline of Production and on the labeling should be consistent. The full instructions for the proper use of the product should indicate the youngest age animals for which the product is both safe and efficacious.

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr.  
Director  
Center for Veterinary Biologics